UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,945	11/26/2003	John J. Price	016434-095400 (ETH-5089)	9633
67395 7590 02/05/2008 . GREENBERG TRAURIG, LLP 200 PARK AVE.			EXAMINER	
			TYSON, MELANIE RUANO	
P.O. BOX 677 FLORHAM PARK, NJ 07932		·	ART UNIT	PAPER NUMBER
	,		3773	
		•		
	•		MAIL DATE	DELIVERY MODE
			02/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		· · · · · · · · · · · · · · · · · · ·				
	Application No.	Applicant(s)				
	10/722,945	PRICE, JOHN J.				
Office Action Summary	Examiner	Art Unit				
	Melanie Tyson	3773				
The MAILING DATE of this communication appeariod for Reply	pears on the cover sheet with	the correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period  - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATION OF THIS COMMUNICATION OF THE COMMUNICATION OF	ATION.  lly be timely filed  HS from the mailing date of this communication.  NDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 25 C	October 2007.					
2a) ☐ This action is <b>FINAL</b> . 2b) ☒ This	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.					
·—	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under	Ex parte Quayle, 1935 C.D.	11, 453 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-8 and 10-31</u> is/are pending in the a	application.	•				
4a) Of the above claim(s) <u>13 and 15-21</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-8,10-12,14, and 22-31</u> is/are reject	6)⊠ Claim(s) <u>1-8,10-12,14, and 22-31</u> is/are rejected.					
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/o	or election requirement.					
Application Papers						
9) The specification is objected to by the Examine	er.	·				
10) The drawing(s) filed on is/are: a) acc	•	y the Examiner.				
Applicant may not request that any objection to the	e drawing(s) be held in abeyand	e. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correct	ction is required if the drawing(s	) is objected to. See 37 CFR 1.121(d).				
11)☐ The oath or declaration is objected to by the E	xaminer. Note the attached	Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of:	n priority under 35 U.S.C. §	119(a)-(d) or (f).				
<ol> <li>Certified copies of the priority documen</li> </ol>	ts have been received.					
<ol><li>Certified copies of the priority documen</li></ol>	ts have been received in Ap	plication No				
3. Copies of the certified copies of the price	ority documents have been r	eceived in this National Stage				
application from the International Burea						
* See the attached detailed Office action for a list	t of the certified copies not re	eceived.				
Attachment(s)		·				
1) Notice of References Cited (PTO-892)	4) 🔲 Interview Su	mmary (PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)		/Mail Date ormal Patent Application				
Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date	6) Other:					

10/722,945 Art Unit: 3773

## **DETAILED ACTION**

## Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 October 2007 has been entered. Claims 13 and 15-21 remain withdrawn from consideration as being directed to a non-elected invention and/or a non-elected species.

# Response to Arguments

2. Applicant's arguments with respect to claims 1-8, 10-12, 14, and 22-31 have been considered but are most in view of the new ground(s) of rejection.

# Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.

10/722,945 Art Unit: 3773

- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 5. Claims 1, 10-12, 14, 22-26, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morton (1,558,037).

Morton discloses an armed suture (see entire document) comprising a needle (1) having first (top end) and second (pointed end) opposed ends and a blind hole (2) formed in the first end and extending longitudinally, the hole including a sidewall and a bottom wall (flat portion) disposed at a location intermediate the opposed ends and having a first diameter proximate the first end (top end) and a second diameter distal to the first end that is greater than the first diameter (for example, see Figure 3 and page 1, lines 29-31), and a suture (4) having an end inserted into the hole.

Morton discloses an adhesive (cement) that upon setting adheres to the suture material anchoring the suture in the hole (for example, see page 2, lines 34-40), thus discloses an adhesive having a viscosity permitting the suture to be inserted into the hole and when cured (when set or dried) bonds the suture to the needle forming a mechanical lock therewith. Morton further discloses an alternate embodiment in which the inside of the hole is scarified (or roughened bond increasing means; see claims 1 and 22) in such a matter as to provide adequate anchorage of the suture therein (for example, see page 2, lines 60-63). It is well within the general knowledge of one having ordinary skill in the art to combine prior art elements to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the blind hole of Morton with a roughened surface

10/722,945 Art Unit: 3773

and an adhesive. Doing so would provide greater anchorage between the hole and adhesive, in turn enhancing anchorage between the suture and the hole, thus further reducing the risk of the suture detaching from the needle during use.

Regarding claim 10, Morton discloses the needle may be swaged such that wall surrounding the hole is tapered (for example, see page 2, lines 50-53). Regarding claim 12, Morton does not disclose the hole is polished after scarified, therefore, it is inherent that the hole is unpolished in this embodiment. Otherwise, the advantages of scarifying would be eliminated in that polishing would provide a smooth surface. Regarding claim 14, Morton discloses the suture may comprise a suture that is commonly employed in surgery (for example, see page 2, lines 54-55), and monofilament sutures are commonly used in surgery (for example, see Dery's patent 3,394,704; column 3, lines 16-18). Regarding claim 31, Morton discloses the hole is a truncated cone tapering toward the neck (for example, see page 1, lines 27-31), thus comprises a bottle-shape. Morton further discloses the adhesive conforms to the shape of the recess when set (for example, see page 2, lines 38-39), thus also comprising a bottle-shape.

Claims 11 and 23-25 are being treated as product by process limitations, in that "said suture hole is formed by laser drilling," "said roughened portion is reamed," "said roughened portion is laser drilled," and "said roughened portion is etched," refers to the process of forming the suture hole and its surface and not to the final product created. As set forth in MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in

10/722,945 Art Unit: 3773

the product-by-process claim is the same as or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695,698,227 USPQ 964,966 (Fed. Cir. 1985).

Examiner has evaluated the product claim without giving much weight to the method of its manufacture. Therefore, in this case, an armed suture as described above wherein the suture hole is formed by laser drilling, and the roughened surface is reamed, laser drilled, or etched, is directed to the method of making the armed suture hole and its roughened surface and not to the final product made. It appears that the product disclosed by Morton would be the same or similar as that claimed; especially since both applicant's product and the prior art product have the same final structure of an armed suture comprising a suture hole having a roughened surface.

Regarding claims 26 and 31, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide the roughened bottom wall with a conical shape and tip. Applicant has not disclosed that a conical shape and tip provides an advantage, is used for a particular purpose, or solves a stated problem. Therefore, it would have been obvious to modify the shape of Morton's bottom roughened wall to obtain the invention as specified in claims 26 and 31. Furthermore, Morton discloses the hole may be drilled and metal drills having fluted tips that conventionally form suture holding bores with cone-shaped bottom walls are well known in the art (for example, see Messer et al.'s patent 3,910,282).

6. Claims 2-8 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morton as applied to claim 1 above, and further in view of Korthoff et al.

10/722,945 Art Unit: 3773

(5,156,615). Morton discloses a device as described above, however, fails to disclose the adhesive is cyanoacrylate.

Korthoff discloses bonding a suture attached to a needle using adhesives (see entire document). With respect to claims 2-8, Korthoff teaches that cyanoacrylate (which is *curable* by exposure to electromagnetic radiation, such as UV light, and further *curable* by a second curative agent, such as water or heat) is a preferred adhesive for bonding the suture within a hole in the needle, since cyanoacrylate possesses excellent adhesive characteristics (for example, see column 9, lines 18-23). It is well within the general knowledge of one having ordinary skill in the art to substitute one known element for another to obtain predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the adhesive disclosed by Morton with cyanoacrylate as taught by Korthoff. Doing so would further enhance the bond, thus further reducing the risk of the suture detaching from the needle during use.

With further respect to claims 27-29, Applicant admits that a low viscosity, UV-curable, cyanoacrylate adhesive having a cyanoacrylate secondary cure mechanism is well known and is available under the name LOCTITE Product 4302. It is well within the general knowledge of one having ordinary skill in the art to choose from a finite number of identified, predictable solutions, with a reasonable expectation of success. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to try the cyanoacrylate adhesive claimed to further enhance the bond between the suture and needle.

## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Friday 9-5:30 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson MT
January 23, 2008

(JACKIE) TAN-UYEN HO SUPERVISORY PATENT EXAMINER